

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION OPIATE  
LITIGATION

This document relates to:

*The Blackfeet Tribe of the Blackfeet Indian  
Reservation v. AmerisourceBergen Drug  
Corp., et al.*  
Case No. 18-op-45749

MDL No. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**REPLY IN SUPPORT OF GENERIC MANUFACTURERS'  
MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT**

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## I. INTRODUCTION

Plaintiff's Opposition confirms that, in essence, Plaintiff's marketing-related claims against the Generic Manufacturers rest upon a failure-to-communicate or failure-to-warn theory—that the Generic Manufacturers should have affirmatively provided warnings beyond the labels of their generic medicines to further explain the risks of opioids contained in those labels and to correct any false statements in the marketplace made about opioids.<sup>1</sup> (Opposition (“Opp.”), ECF No. 1017, at 24). But under controlling decisions from the Supreme Court, the Sixth Circuit, and numerous other Circuit Courts—including *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917 (6th Cir. 2014), *Morris v. PLIVA*, 713 F.3d 774 (5th Cir. 2013), and *Guarino v. Wyeth, LLC*, 719 F.3d 1245 (11th Cir. 2013)—these claims are preempted because of the “duty of sameness” imposed by federal law. Federal law prohibits Generic Manufacturers from issuing communications about their generic medicines to physicians or others that were not previously issued by brand manufacturers.

Like the Muscogee Nation, Plaintiff argues that the sameness requirement imposed by federal law did not prohibit the Generic Manufacturers from sending unilateral communications to physicians and others, at least those communications that did not “conflict[] with or differ[] in

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<sup>1</sup> The Generic Manufacturers are Watson Laboratories, Inc. (“Watson”), Actavis Pharma, Inc. (“Actavis Pharma”), Actavis LLC (“Actavis LLC”), Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc. (collectively, the “Generic Manufacturers”). The claims against the Generic Manufacturers fail for the reasons set forth in the Manufacturers’ Joint Motion to Dismiss (“Joint MTD”) and Joint Reply (“Joint Reply”), which are incorporated herein by reference, but the claims against the Generic Manufacturers are particularly deficient for the reasons stated herein and their motion to dismiss. Mallinckrodt LLC, SpecGx LLC, and Teva Pharmaceuticals USA, Inc. (“Teva USA”) also join this reply to the extent Plaintiff’s claims rest on allegations regarding their generic products. *See e.g.*, FAC ¶¶ 47-49, 76-78 (asserting that Teva USA, Mallinckrodt LLC, and SpecGx LLC manufacture generic opioid products). For purposes of this memorandum, emphasis in quotations is added, and internal citations, quotation marks, and alterations are omitted.

content from any information on the FDA-approved label for any opioid.” (Opp. 23). But the Sixth Circuit has expressly rejected this argument, recognizing that “[u]nder federal law, *the inquiry is whether the brand-name manufacturers sent out a warning*, not whether the proposed warning to be disseminated [by the generic manufacturer] contains substantially similar information as the label.” *Darvocet*, 756 F.3d at 933 (quoting *Morris*, 713 F.3d at 777). Under federal law, generic manufacturers could not make any warnings about their generic medicines different than those provided by brand manufacturers, including sending unilateral communications about their generic medicines. Given this preemptive sameness requirement, all marketing-related claims against the Generic Manufacturers must be dismissed.<sup>2</sup>

Unable to meaningfully distinguish these controlling cases, Plaintiff relies exclusively upon two irrelevant decisions—*Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013), and *Teva Pharm. USA, Inc. v. Superior Court*, 158 Cal. Rptr. 3d 150 (Cal. Ct. App. 2013). Both of these cases addressed an entirely different situation: a generic manufacturer’s alleged failure to update its label for a generic medicine after the brand manufacturer changed its label. In those circumstances, the courts held that the “duty of sameness” did not prohibit a change by the generic manufacturer. But Plaintiff does not and cannot allege that the FDA-approved labels for the Generic Manufacturers’ opioid medicines differed from their brand equivalents in this case. In fact, Plaintiff does not allege any facts about the generic medicines sold by the Generic Manufacturers, much less the labeling history of any of those medicines.

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<sup>2</sup> Plaintiff expressly does not address (Opp. 30 n. 12), and, thus, does not dispute, that if the state law marketing claims fail, so does Plaintiff’s RICO marketing claim. *See Pom Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2236 (2014) (preemption analysis informs whether federal statute precludes claim under another federal statute). Of course, Generic Manufacturers cannot be penalized under RICO for complying with the Food Drug & Cosmetic Act (“FDCA”).

In a desperate attempt to avoid preemption, the Opposition resorts to contradiction—that, in addition to failing to communicate the risks of their generic opioids to physicians, the Generic Manufacturers also made false misrepresentations about their generic opioid medicines. But, as in *Muscogee*, the Opposition fails to identify a single interaction between any Generic Manufacturer and any prescriber in Montana (or elsewhere); a single false or misleading statement made by any Generic Manufacturer; or a single opioid prescription that was somehow written because of a false or misleading statement made by any Generic Manufacturer. The Complaint barely even mentions any Generic Manufacturer by name. Nor can Plaintiff plead these fundamental details, given that the Generic Manufacturers “compete on price ***and avoid marketing*** to physicians because the costs of such marketing severely impact their ability to offer the significantly lower prices upon which they compete.” *New York ex rel. Schneiderman v. Actavis, PLC*, No. 14-cv-7473, 2014 WL 7015198, at \*27 (S.D.N.Y. Dec. 11, 2014), *aff’d*, 787 F.3d 638 (2d Cir. 2015). The absence of these basic facts showing any marketing by Generic Manufacturers is not a factual dispute for a later time—it is a basis for dismissal now.

Lastly, notwithstanding its failure to plead any specific conduct by any specific Generic Manufacturer, Plaintiff argues that it has properly pled claims for failure to report suspicious orders or prevent diversion. But, as discussed in the Generic Manufacturers’ opening brief, these claims are nothing more than improper attempts to enforce violations of federal and state law for which no private right of action exists. Worse yet, the Opposition does not identify a single fact to show that any Generic Manufacturer failed to report a suspicious order or that any suspicious order caused them harm. Instead, the Opposition confirms that Plaintiff’s claims rest exclusively upon conclusory group-pled allegations about all Defendants and the flawed position that Generic Manufacturers can be held responsible for the conduct of others. Under *Bell Atl. Corp. v. Twombly*,

550 U.S. 544 (2007), *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and their progeny, these claims must be dismissed, too.

## **II. ARGUMENT**

### **A. Plaintiff’s Marketing Claims Against The Generic Manufacturers (Counts I And III-X) Fail On Preemption Grounds.**

Plaintiff concedes that its marketing claims against the Generic Manufacturers are based on a failure-to-communicate theory—that the Generic Manufacturers “were obligated to correct or counter the serious and pervasive misrepresentations in the market through ‘Dear Doctor’ letters or other forms of communication[s] with doctors.” (Opp. 23; *id.* at 21 (arguing that Generic Manufacturers failed to unilaterally send “doctors and patients” communications “with adequate and truthful warnings that did not differ in content from the approved warnings in the labels” of generic medicines); *id.* at 24 (Generic Manufacturers “were required, to the extent possible, to correct these falsehoods” made in the market regarding the “true risks of these drugs.”)). But as the Generic Manufacturers have explained, the Supreme Court, the Sixth Circuit, and other courts have rejected these failure-to-communicate claims as preempted by federal law. (Generic Manufacturer Mot. To Dismiss (“GM MTD”), ECF No. 930-1, at 9-12).

*Mensing* made clear that generic labeling—including its warnings and other safety-related information—must be “the same as the labeling approved for the [brand-name] drug.” *Mensing*, 564 U.S. at 612-13. As a result, failure-to-communicate claims against generic manufacturers are preempted because the sameness requirement prohibits generic manufacturers from going beyond their branded counterparts’ warnings. Applying this principle, the *Mensing* Court expressly held that the sameness requirement prohibited generic manufacturers from unilaterally providing

additional warnings through “Dear Doctor” letters to physicians.<sup>3</sup> Doing so violates the sameness requirement because “if generic manufacturers, but not the brand-name manufacturer[s], sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly ‘misleading.’” *Id.* at 615; *see also Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1287-88 (10th Cir. 2013) (applying sameness requirement to hold claims against generic manufacturer preempted).

*Darvocet* is directly on point. There, the Sixth Circuit affirmed the dismissal of claims based upon the precise theory alleged here: that generic manufacturers should have sent “Dear Doctor” letters or other communications to healthcare professionals regarding the risks of their generic medicines when such communications were *not* sent by brand manufacturers. *Darvocet*, 756 F.3d at 932. Applying *Mensing*, the Sixth Circuit held that requiring generic manufacturers to send these unilateral communications would “violate the duty of sameness.” *Id.* at 933. Critically, the Sixth Circuit agreed with numerous other Circuit decisions and emphasized that “[u]nder federal law, ***the inquiry is whether the brand-name manufacturers sent out a warning, not whether*** the proposed warning to be disseminated [by the generic manufacturer] contains substantially similar information as the label.” *Id.* (collecting cases). Thus, “[***b]ecause no brand-name manufacturer sent a warning*** . . . the generic manufacturers were not at liberty to do so.” *Id.*; *see Morris*, 713 F.3d at 777 (applying rule to dismiss similar failure-to-communicate claims based upon alleged failure of generic manufacturer to send unilateral communications about content of current label); *Guarino v.* 719 F.3d at 1249-50 (same).

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<sup>3</sup> “Dear Doctor” letters are communications used by manufacturers to notify health care providers about new or updated warnings regarding a drug. *See* 21 C.F.R. § 200.5 (“Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care.”).

Just as in *Darvocet*, the Generic Manufacturers could not have unilaterally sent any additional communications or warnings regarding their generic opioids because no brand name manufacturers did so. Preemption does not rest upon the proposed content of any additional warning that generic manufacturers purportedly should have sent, but, instead, on whether the brand manufacturers sent such a warning. If the brand manufacturers did not send such a communication, the sameness requirement precludes generic manufacturers from doing so, too. *Darvocet*, 756 F.3d at 932; *Morris*, 713 F.3d at 777; *Guarino v.* 719 F.3d at 1249. Notably, despite discussing *Darvocet*, Plaintiff simply ignores its controlling logic (and the very cases it cites with approval). Yet it is this logic that defeats Plaintiff’s marketing claims. *See Darvocet*, 756 F.3d at 932 (affirming dismissal because “generic manufacturers cannot send ‘Dear Doctor’ Letters unless their brand counterparts do so first”).

Instead of offering any meaningful analysis to distinguish *Mensing*, *Darvocet*, *Morris*, *Guarino*, and their progeny, Plaintiff tries to distort the holding in *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013). (Opp. 22-23). That decision is entirely inapposite. In *Fulgenzi*, the generic manufacturer failed for years to update the label of its generic medicine to match that of the branded label, as required by federal law. The Sixth Circuit only found no preemption to the extent plaintiff was arguing the inadequacy of the generic manufacturer’s warning because “it did not include the language contained in the updated Reglan label from 2004.” *Id.* at 584; *see also id.* at 588.<sup>4</sup> Indeed, since *Fulgenzi* was decided, both the Sixth Circuit and other Circuits have reaffirmed that *Fulgenzi* is limited to certain failure-to-update claims—that is, those against a

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<sup>4</sup> The *Fulgenzi* Court also made clear that claims against a “generic-drug manufacturer whose branded counterpart had not updated its warning [in its FDA-approved label] . . . would be preempted under an impossibility theory” under *Mensing*. *Fulgenzi*, 711 F.3d at 587. Thus, to the extent Plaintiff now claims that the Generic Manufacturers should have unilaterally updated any warnings, *Fulgenzi* precludes that theory of liability.

generic manufacturer which fails to update a generic label after a change to the label of the brand equivalent. *See Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 399 (6th Cir. 2013) (recognizing *Fulgenzi* applies to failure to update or “conform” claims, yet affirming dismissal of such claims for failure to plead sufficient facts); *Guarino*, 719 F.3d at 1250 n.2 (“In the present case, Guarino does not allege that Teva failed to update its label once the Brand Manufacturers strengthened it, so *Fulgenzi* is inapplicable.”).

Of course, *Fulgenzi* has nothing to do with this case. Plaintiff here does not and cannot allege that the Generic Manufacturers failed to update the labels of their opioid medicines after a change in the FDA-approved labels of their brand equivalents. Nor do they allege that the actual labels for the generic medicines manufactured by the Generic Manufacturers were not the same as their brand equivalents at any point in time. In fact, Plaintiff does not even identify a single generic medicine sold by any of the Generic Manufacturers, much less the labeling history of those medicines.<sup>5</sup>

The only other decision upon which Plaintiff relies—*Teva Pharm. USA, Inc. v. Superior Court*, 158 Cal. Rptr. 3d 150 (Cal. Ct. App. 2013)—is another failure-to-update case, and from a (non-binding) California intermediate appellate court. It, too, has no relevance here. There, the plaintiff alleged that the brand-name drug label for Fosamax was updated, but that the manufacturers of the generic equivalent failed to update their products’ labels accordingly, such that the generic drug label did not match the brand-name drug label. *Id.* at 153. The California

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<sup>5</sup> In fact, in *Strayhorn*, the Sixth Circuit affirmed the dismissal of a complaint that actually made allegations in support of a failure-to-conform claim, including that “several” of the Generic Manufacturers “fail[ed] to include information present in the label for the RLD and fail[ed] to implement changes to their own labels,” and that some generic manufacturers “waited years to conform their labels to the RLD label.” *Id.* at 399. But even those allegations were held insufficient under *Iqbal* and *Twombly*. Clearly, Plaintiff here has not pled such a claim since there are no allegations whatsoever to support such a theory.

Court of Appeals held that federal law did not preempt these claims because, given the particularized allegations, it was possible for the generic manufacturers to comply both with the federal sameness requirement (*i.e.*, their federal duty to update the labels to match the branded label) and with their state law duties. *Id.* at 157-58 (holding that it was possible for generic manufacturers “to comply with both a federal duty to make their labels match the Fosamax label . . . and a state tort law duty”); *id.* at 162 (noting that generic manufacturers could provide update to “health care professionals of the risks identified in the 2010 and 2011 Fosamax label changes”).

Putting aside the propriety of that decision, Plaintiff distorts its holding, arguing that *Teva* really stands for the proposition that generic manufacturers can be ***unilaterally*** obligated to send “‘Dear Doctor’ letters and similar communications” so long as those communications do not contain new or additional information not contained within the “name-brand” label. (Opp. 26). Not so. *Teva* was a basic failure-to-update case—a theory that Plaintiff does not and cannot allege here. Under *Mensing*, *Darvocet*, *Morris*, *Guarino*, and their progeny, Generic Manufacturers were not permitted to send the very communications sought by Plaintiff unless brand manufacturers had already done so—and Plaintiff does not allege anywhere in the FAC that any brand manufacturers had done so. As a result, all of Plaintiff’s marketing-related claims fail. *See, e.g., Guarino*, 719 F.3d at 1249 (affirming dismissal of claim that generic manufacturer unilaterally failed to send communication about content of current label and holding that “[b]ecause the duty of sameness prohibits the generic manufacturers from taking such action unilaterally, they are dependent on brand-names taking the lead”).<sup>6</sup>

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<sup>6</sup> Magistrate Judge Ruiz’s Report and Recommendation (the “Report”) in *Summit County* does not alter this conclusion. (ECF No. 1025, at 49). *Summit County* did not assert any failure to communicate or warn claims against the Generic Manufacturers. Thus, the Report did not address—and could not have addressed—the preemption arguments and issues raised here. For this reason and others, the cases cited to in the Report are entirely inapposite. For example, in

Put simply, controlling Sixth Circuit law holds that “claims [that] boil down to an alleged duty to provide additional information” for generic medicines are “essentially failure-to-warn claims that are preempted under *Mensing*.” *Strayhorn*, 737 F.3d at 397. This controlling principle bars Plaintiff’s marketing-related claims against the Generic Manufacturers.

**B. Plaintiff’s False Marketing Claims (Counts I And III-X) Fail Because Plaintiff Does Not Allege Any False Marketing By The Generic Manufacturers, Much Less With The Specificity Required By Rule 9(b).**

It is a well-settled principle that Generic Manufacturers do not market generic medicines because of drug substitution laws and pricing, which remove the financial incentive to do so. (GM MTD, at 4-6, 8-12). While Plaintiff disputes that proposition (Opp. 63-64), courts must draw on “judicial experience and common sense” in determining whether a claim is plausible. *Iqbal*, 556 U.S. at 679 (applying principle). As the Second Circuit recognized, “expenditures by generics on marketing would be impractical and ineffective because a generic manufacturer promoting a product would have no way to ensure that a pharmacist would substitute its product, rather than one made by one of its generic competitors.” *Actavis PLC*, 787 F.3d at 656.

The Opposition validates this common-sense principle. Plaintiff does not identify a single statement attributable to any of the Generic Manufacturers about one of their generic medicines; a single statement made by a Generic Manufacturer that reached a Montana doctor, a tribal citizen

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*Arters v. Sandoz Inc.*, 921 F.Supp.2d 813 (S.D. Ohio 2013), the court found no preemption as to the fraudulent off-label marketing claim, but held “[t]o the extent plaintiffs’ claims rely on defendants’ failure to warn consumers of the risks of amiodarone, they are preempted by the FDCA.” *Id.* at 820. Likewise, *Beavers-Gabriel v. Medtronic, Inc.*, No. CIV 13-00686 JMS, 2015 WL 143944, at \*6 (D. Haw. Jan 9, 2015), is inapposite because it addressed the preemption of claims against a medical device manufacturer under an entirely separate statutory scheme. And in *Priest v. Sandoz, Inc.*, No. A-15-CV-00822-LY-ML, 2016 WL 11162903, at \*7 (W.D. Tex. Dec. 29, 2016), *report and recommendation adopted*, 2016 WL 8896188 (W.D. Tex. Jan. 31, 2017), the court discussed preemption in the context of fraudulent marketing—not an alleged failure by a generic manufacturer to communicate information about its generic medicines.

who received an opioid prescription, or Plaintiff itself; or any of the requisite details of any fraudulent conduct, such as who made an allegedly false statement, when, to whom, and why it is purportedly false. Plaintiff cannot bring false marketing claims against Generic Manufacturers when there is no alleged marketing—much less false marketing. *See Darvocet*, 756 F.3d at 932 (affirming dismissal of false marketing claims against all “Generic Manufacturers” because plaintiffs failed to plead specific facts against each defendant to support legal theory).

In an effort to reverse their pleading burden, Plaintiff argues that the “Generic Manufacturers will have the opportunity to deny, and to attempt to disprove the allegations of the Complaint with respect to their participation in the fraudulent marketing of opioids.” (Opp. 64). But that is precisely the problem—there are no factual allegations to dispute. Plaintiff has not pled any such facts about the “participation” of any Generic Manufacturer in any “fraudulent marketing” to state a plausible claim. And Plaintiff certainly has not done so with the specificity demanded by Rule 9(b), which requires specific acts of fraud by each Generic Manufacturer. *See, e.g., United States ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 505-06 (6th Cir. 2008) (dismissing claims for failure to satisfy Rule 9(b)).

Remarkably, Plaintiff argues that it has satisfied Rule 9(b) because “Generic Manufacturers are subsidiaries and sibling companies to name-brand manufacturers” and the Complaint groups generic and name-brand manufacturers together under a variety of fictional names, including “Mallinckrodt” and “Actavis,” and then makes allegations about these fictional entities. (Opp. 65). But this group pleading tactic is entirely improper. *See Hoover v. Langston Equip. Assocs., Inc.*, 958 F.2d 742, 745 (6th Cir. 1992) (affirming dismissal because “plaintiffs had not alleged with specificity who had made particular misrepresentations and when they were made but rather plaintiffs had articulated general averments of fraud attributed to “the defendants”). Indeed, the

Sixth Circuit rejected this very tactic in *Darvocet*, where it held that lumping various generic manufacturers together was inappropriate and failed to identify “which” generic manufacturers purportedly “did not timely implement the warnings” and “caused the injuries.” *Darvocet*, 756 F.3d at 932. Just as group pleading as to various generic manufacturers is improper, so is group pleading that lumps ***both*** generic and brand manufacturers together without differentiation.

Plaintiff also contends that it has satisfied its Rule 9(b) burden as to the Generic Manufacturers because it alleges that all “Marketing Defendants engaged in unbranded advertising and promotion.” (Opp. 65). But this is yet another layer of improper group pleading—lumping the Generic Manufacturers together with even more independent (and competitor) manufacturers. Tellingly, none of the allegations cited in the Opposition identifies a single statement by Watson, Actavis Pharma, Actavis LLC, or any other Generic Manufacturer about any of their generic medicines, much less to whom any such statement was made, when, where, or how it was supposedly false. Although Plaintiff argues that the Court can simply “infer” such false marketing because “each of the Generic Manufacturers is affiliated with a branded manufacturer” (*id.* at 66), Plaintiff fails to cite a single case for this proposition, which ignores federal pleading standards and the bedrock principle that companies are not responsible for the acts of their parents or affiliates. *See United States v. Bestfoods*, 524 U.S. 51, 61 (1998).

Because the Generic Manufacturers do not promote generic medicines and there is not a single factual allegation to show that they did so (much less with the specificity required by Rule 9(b)), Plaintiff’s false marketing claims fail as a matter of law.

**C. Plaintiff’s Claims (Counts II-X) Based Upon The Failure To Prevent Diversion Also Fail.**

The diversion claims against the Generic Manufacturers fail for the many reasons stated in the briefing in support of the Joint MTD and the *Muscogee* MTD, including that there is no private

cause of action to enforce violations of the federal Controlled Substances Act (“CSA”) and Montana law and Plaintiff cannot use common law claims to do so. (GM MTD, at 13; Joint MTD, at Part I, II.C, V.A.2; Joint Reply, ECF No. 1089, at Part I, II, III, V; *Muscogee* MTD, at 24; *Muscogee* Reply, at 11-14). But these claims are particularly deficient as to the Generic Manufacturers because, like the claims in *Muscogee*, there is not a single factual allegation pled against any Generic Manufacturer regarding its failure to comply with any diversion monitoring or reporting allegations.

Plaintiff does not dispute the absence of such facts, yet asks the Court to ignore this fundamental failure because only “notice-pleading” is required. (Opp. 66). But *Iqbal* requires this Court to disregard “legal conclusions” and “conclusory statements,” and requires *factual* allegations to plead a plausible inference of wrongdoing against each defendant. *Iqbal*, 556 U.S. at 677–79. Plaintiff admittedly fails to do so. Indeed, the Opposition fails to identify a single suspicious order that any Generic Manufacturer failed to report; a single misleading statement or omission by any Generic Manufacturer regarding any federal or state diversion monitoring obligation (much less when they were made and to whom); or how any alleged failure to report by any Generic Manufacturer caused Plaintiff to incur some harm. *Darvocet*, 756 F.3d at 931 (“To survive a motion to dismiss, a complaint must plead ‘facts’ that create a ‘plausible inference’ of wrongdoing” against each defendant).

In a single paragraph, the Opposition argues that it has satisfied its pleading burden based upon two allegations—that “Defendants failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids following into communities across America” and that “Defendants continued to pump massive quantities of opioids despite their [legal] obligations to control the supply, prevent diversion, report and take steps to halt suspicious orders.” (Opp. 67

(quoting FAC ¶ 564)). But even if the Court were to ignore the improper group pleading, these allegations offer no facts about any Generic Manufacturer. They are analogous to the conclusory allegation in *Iqbal* that a particular defendant “was the ‘principal architect’” of a discriminatory policy and acted out of discriminatory motive, *Iqbal*, 556 U.S. at 680–81; or the conclusory allegation in *Twombly* that the defendant conspired with its competitors, *Twombly*, 550 U.S. at 557; or the conclusory allegation in *Darvocet* that the defendants “failed to update their warnings,” *Darvocet*, 756 F.3d at 932—all of which were disregarded as a matter of law as too conclusory and deemed insufficient to state a plausible claim. This Court should do the same and dismiss all diversion-related claims against the Generic Manufacturers.

**D. The Amici Brief Does Not And Cannot Support Any Legal Claims Against The Generic Manufacturers.**

The Amici Brief in opposition to the Defendants’ pending motions to dismiss fails to save Plaintiff’s defective claims. (ECF No. 1026). Although the Amici Brief purports to detail what the Amici believe to be the historical, political, legal and factual context for the “opioid epidemic” and its impact on various tribes, it is devoid of any legal arguments regarding the legal viability of the Plaintiff’s claims against the Generic Manufacturers (or anyone else). It ignores the federal statutory and regulatory scheme imposing the sameness requirement on Generic Manufacturers and giving rise to federal preemption over all claims against the Generic Manufacturers. And nowhere in its discussion does the Amici Brief link any alleged misconduct or resulting harm to any of the Generic Manufacturers—nor can it.

**III. CONCLUSION**

For all the reasons set forth above and in the Manufacturers’ Joint MTD and Joint Reply, all claims against Generic Manufacturers should be dismissed with prejudice.

Dated: November 2, 2018

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**LOCAL RULE 7.1(F) CERTIFICATION**

I certify that this case has been assigned to the “litigation track” pursuant to CMO One and that this Memorandum adheres to the page limitations set forth in CMO One § 6(f), CMO Four at 2-3, L.R. 7.1(f), and the Court’s July 26, 2018 Order.

Dated: November 2, 2018

By: /s/ Steven A. Reed  
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**CERTIFICATE OF SERVICE**

I hereby certify that on November 2, 2018, a copy of the foregoing **Reply in Support of Generic Manufacturers' Motion to Dismiss Plaintiff's First Amended Complaint** was filed electronically in MDL Master Docket No. 17-md-2804 and in No. 1:18-op-45749-DAP. Notice of this filing was sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

By: /s/ Steven A. Reed

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